

RAPID PLEURODESIS USING SMALL BORE PIGTAIL CATHETER AND BLEOMYCIN IN MALIGNANT PLEURAL EFFUSIONS: A CASE SERIES

BY

DR MOHD NIZAM MD HASHIM

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VI ABBREVIATIONS

MPE	Malignant Pleural Effusion
HUSM	Hospital Universiti Sains Malaysia
HRPZ II	Hospital Raja Perempuan Zainab II
CXR	Chest X-ray
CT Scan	Computed tomography scan
GCS	Glasgow Coma Scale
MRI	Magnetic Resonance Imaging
Fr	French Unit

VII ABSTRAK

Pengeluaran cecair dari pleura adalah rawatan pilihan untuk pesakit yang mempunyai simptom sukar bernafas disebabkan oleh penyakit malignant pleural effusion. Kebiasaannya, rawatan untuk pleural effusion adalah dengan memasukkan tiub bersaiz besar ke dalam ruang selaput paru-paru untuk mengeluarkan cecair yang terkumpul sebelum melakukan 'pleurodesis' iaitu proses perlekatan selaput paru-paru menggunakan ubat. Tujuan kajian prospektif ini adalah untuk menilai keberkesanan proses perlekatan selaput paru-paru dengan menggunakan tiub bersaiz kecil (Mar Flow® CH12 'pigtail catheter') dan bleomycin untuk pesakit yang mengalami penyakit barah paru-paru berair. Proses perlekatan paru-paru dengan bleomycin dilakukan dalam tempoh dua puluh empat jam selepas tiub 'pigtail' dimasukkan. Pesakit akan dinilai semula pada empat minggu selepas proses perlekatan pleura dijalankan berserta dengan sinar-X dada. Keberkesanan proses perlekatan pleura dinilai berdasarkan kepada keputusan sinar-X dada. Rawatan dikategorikan sebagai berjaya ('success') sekiranya imej sinar-X dada tidak menunjukkan pertambahan cecair di antara pleura. Rawatan dikategorikan sebagai separuh berjaya ('partial success') sekiranya imej sinar-X dada menunjukkan pertambahan cecair tetapi pesakit tidak memerlukan rawatan untuk mengeluarkan cecair dari ruang pleura. Pesakit yang tidak memenuhi kriteria di atas dikira sebagai tidak berjaya ('failed'). Lima pesakit yang menghidap penyakit malignant pleural effusion dari Hospital Universiti Sains Malaysia dan Hospital Raja Perempuan Zainab II terlibat dalam kajian prospektif ini. Purata umur pesakit yang terlibat adalah 53.6 tahun and purata masa yang diperlukan untuk menamatkan proses perlekatan pleura adalah 9.5 jam. Antara penyakit primer yang dihidapi oleh pesakit-pesakit yang terlibat adalah kanser ovari, kanser payu dara dan kanser usus. Daripada 5 pesakit yang terlibat, tiga pesakit (60%)

dikategorikan sebagai berjaya, satu pesakit (20%) dikategorikan sebagai separuh berjaya dan satu pesakit (20%) dikategorikan sebagai tidak berjaya selepas proses perlekatan pleura dilakukan.

ABSTRACT

Pleural drainage is the treatment of choice for patients presented with symptomatic malignant pleural effusion. The conventional method of treatment is insertion of large bore thoracostomy tube (chest tube) before proceeding to chemical pleurodesis. The aim of this preliminary prospective study was to investigate the success rate of performing pleurodesis using a small bore pigtail catheter (Mar Flow® CH12) in patients with malignant pleural effusion. Pleurodesis was performed within twenty four hours after insertion of pigtail catheter with bleomycin as sclerosing agent. Patients were follow-up at four weeks post pleurodesis with chest radiography. The intervention was scored as “successful” if no radiographic evidence of fluid reaccumulation was noted at four weeks. A “partial success” score indicated accumulation of fluid that did not produce symptoms and did not require repeat pleural drainage of any sort. All other outcomes were scored as “unsuccessful”. Five patients with malignant pleural effusion from Hospital Universiti Sains Malaysia and Hospital Raja Perempuan Zainab II were included in this study with mean age of 53.6 year old. The primary diseases include breast, lung, ovarian and colon cancers. The mean time of pleurodesis was 9.5 hours. Of the five pleurodesis performed, a complete response (“successful”) was seen in three patients (60%), a partial response (“partial success”) was seen in one patient (20%) and one patient (20%) did not respond to rapid pleurodesis. In conclusion, pleurodesis in patients with malignant pleurodesis can be achieved rapidly using small bore pigtail catheter and bleomycin.

1. INTRODUCTION

Malignant pleural effusions (MPEs) are a common complication of advanced malignancies, particularly lung and breast cancer. Lung cancer and breast cancer account approximately seventy five percents of malignant pleural effusions with the remaining twenty five percents representing the cross section of neoplastic disease. The collection of pleural fluids in the pleural space results in significant reduction in lung vital capacity, hence causing dyspnoea and reduction in quality of life (Lynch Jr, 1993). Treatment goals for these patients should focus on symptomatic relief or elimination of hospitalization, and efficient use of medical care resources (Antunes and Neville, 2000). While malignant pleural effusion is often a sign of advanced and progressive cancer, many patients with malignant pleural effusion survive in excess of six months. Furthermore, some patients with malignant pleural effusion such as lymphoma and germ cell tumours can be cured of their malignancy. Thus, control of malignant pleural effusion in a manner which promptly relieves symptoms and maintains quality of life is an important part of the overall management of patients with advanced cancer (Lynch Jr, 1993). The purpose of this study was to determine the successful rate of rapid pleurodesis using small bore pigtail catheter and bleomycin. There were 5 patients with malignant pleural effusion involved in this case series.

1.1 Pathophysiology

Pleural effusions occur between two membranes: the visceral (inner) layer of the pleura attached to the lungs, and the parietal (outer) layer attached to the chest wall. The “pleural space” normally is nonexistent and is lubricated by a slight amount of pleural fluid (10–20 cc) that provides lubrication between the pleura. Fluid (sera) continuously moves from the parietal pleura through the pleural space to be absorbed by the visceral pleura. The fluid is then drained into the lymphatic system. In patients with primary malignancies, metastasis to the pleural space may cause significant shifts or fluid imbalance from derangements in the Starling forces that regulate the re-absorption of fluid within the pleural space. Movement of pleural fluid across the pleural space may involve over 5 to 10 liters per day, and derangements in this movement may increase the normal amount of pleural fluid from 5 to 50 cc to a more significant amount. Other disease processes may also significantly affect the ability of the body to manage its intra-pleural fluid (Putnam Jr, 2002).

1.2 Pleurodesis

Pleurodesis is a treatment that aims to produce fibrosis of the pleura by chemical or mechanical means in order to obliterate the pleural space (Shaw and Agarwal, 2004). The principle behind this approach is that the chest tube drains the pleural space and the sclerosing agent creates a pleuritis that joins the visceral and parietal pleura and prevent

fluid re-accumulation (Lynch Jr, 1993). Hence, to avoid the need for repeated hospitalization for thoracocentesis. Different techniques have been used over the past twenty years with the most commonly used methods employ a chemical sclerosant (irritant) which is instilled in the pleural space either during thoracoscopy or bedside thoracostomy, following complete drainage of the effusion (Shaw and Agarwal, 2004).

A number of different methods have been used for pleural fluid drainage or evacuation and these include thoracocentesis, tube thoracostomy (chest tube), pleuroperitoneal shunting and recently the use of small bore catheters. The most common technique involves the large bore chest tube drainage followed by chemical pleurodesis with various agents. This technique entails significant morbidity including prolonged inpatient hospitalization, limited mobility from the pleural drainage apparatus, fevers from pleural inflammation and significant pain from chest tube and surgical incision (Musani *et al.*, 2004). The principle behind this approach is that the chest tube drains the pleural fluid and the sclerosing agent creates a pleuritis that joins the visceral and parietal pleura and prevent fluid re-accumulation (Lynch Jr, 1993).

1.3 Sclerosing Agents

Effective sclerosing agents share the property of causing a chemical pleuritis. Although many anti-tumour agents have been used successfully as sclerosing agents, it appears that the mechanism of control of effusion is related to their ability to induce a pleuritis

rather than their anti-tumour activity (Lynch Jr, 1993). Various sclerosant agents have been used to achieve pleural symphysis in pleurodesis and these include talc powder, bleomycin, tetracycline, quinacrine, silver nitrate and many more. However, the former three sclerosing agents mentioned were commonly used.

1.3.1 Tetracycline

Tetracycline is a low cost, effective therapy that is well tolerated (Lynch Jr, 1993). This compound controls effusion in between thirty three and eighty four percents of patients treated and it is well distributed throughout the pleural space (Gravelyn *et al.*, 1987, Oszko, 1998). The chief side effects of tetracycline sclerosis are fever (33%) and pain (41%) (Putnam Jr, 2002).

1.3.2 Talc

Talc has an efficacy in the eighty percent to more than ninety percent range and a safe adverse event profile (Colt and Davoudi, October 2008). Of the more than thirty randomized controlled trials comparing different pleurodesis agents, most have favored talc, which is recommended pleurodesis agent of choice in the Cochrane Review (Shaw and Agarwal, 2004). The major concern with talc is the risk of lung inflammation, severe hypoxemia and acute respiratory distress syndrome (Colt and Davoudi, October 2008). There have also been reports that talc can cause empyema, cardiovascular complications such as arrhythmias, cardiac arrest, chest pain, myocardial infarction and hypotension (Lynch Jr, 1993).

1.3.3 Bleomycin

Bleomycin is an anti-tumour antibiotic whose efficacy is related to sclerosing action rather than anti-neoplastic effects. The standard dose of bleomycin is sixty Units intrapleural, with higher doses may be associated with increased toxicity (Lynch Jr, 1993). When it is used in this manner, the effectiveness ranges from sixty to eighty percents at four weeks (Ostrowski and Halsall, 1982). Side effects of intrapleural bleomycin include fever and pain which in a randomized trial, they were similar to tetracycline (Lynch Jr, 1993).

1.4 Methods of Pleural Drainage

A number of different methods have been used for pleural fluid drainage or evacuation and these include thoracentesis, tube thoracostomy (chest tube), pleuroperitoneal shunting and recently the use of small bore catheters. The most common technique involves the large bore chest tube drainage followed by chemical pleurodesis with various agents. This technique entails significant morbidity including prolonged inpatient hospitalization, limited mobility from the pleural drainage apparatus, fevers from pleural inflammation and significant pain from chest tube and surgical incision (Musani *et al.*, 2004)

1.4.1 Thoracocentesis

Thoracocentesis plays an important step in diagnosing and managing malignant pleural effusion. The wisdom of repeated therapeutic thoracocentesis can and should be questioned as symptomatic relief is temporary before the pleural fluid re-accumulate. Thoracocentesis alone was associated with a mean time of effusion recurrence of 4.2 days with the majority recurring in one to three days (Anderson *et al.*, 1974). Repeated thoracocentesis increases the risks of pneumothorax, empyema and pleural fluid loculation. Therapeutic thoracocentesis should thus be reserved for patients who have highly responsive underlying malignancy and will be undergoing chemotherapy or for patients who are severely dyspnoeic with life expectancy of less than one month (Lynch Jr, 1993).

1.4.2 Tube Thoracostomy (Chest Tube)

The most common method to drain malignant pleural effusion has been large bore chest tube drainage (Sahin *et al.*, 2001). This method entails significant morbidity including prolonged inpatient hospitalization, limited mobility from the pleural drainage apparatus, fevers from pleural inflammation and significant pain from chest tube and surgical incision (Musani *et al.*, 2004). Since many patients with malignant pleural effusions have already experienced significant morbidity from chemotherapy and or radiation therapy, it would be ideal to minimize hospitalization and patients discomfort in the process of relieving respiratory symptoms and controlling fluid re-accumulation (Sahin *et al.*, 2001).

1.4.3 Pleuroperitoneal Shunting

The placement of a pleuroperitoneal shunt is an alternative approach that has particular appeal in patients with refractory effusions (Tsang *et al.*, 1990). In this approach, a catheter is placed subcutaneously into the pleural and peritoneal spaces. A pump is manually compressed to drain fluid from the pleura into the peritoneal cavity. This approach may also aid patients when the lung is 'trapped' and unable to re-expand to allow effective sclerosis. Tumor seeding of the peritoneum is less likely to be a major issue in patients who have such advanced malignancy (Lynch Jr, 1993).

1.4.4 Small Bore Catheter

The use of small bore catheter in achieving pleural drainage has been found to be as effective as the large bore catheter. Placement of the large bore chest tube is a surgical procedure that requires blunt dissection often resulting in pain and discomfort during both placement and maintenance of the tube. In a prospective randomized study, it was concluded that pleurodesis in patients with recurrent malignant pleural effusion can be performed with a small percutaneous catheter with an effect to that obtained with a large bore chest tube and with less discomfort for the patient (Clements *et al.*, 1998).

1.5 Rapid Pleurodesis

The typical duration of hospitalization for chemical pleurodesis is five to seven days . Much of this time is a consequences of prolonged chest tube drainage both prior to and immediately following pleurodesis. The primary goal of drainage prior to pleurodesis is to remove sufficient pleural fluid to oppose the pleural surfaces. Some clinicians delay pleurodesis until the rate of chest tube drainage is minimal over twenty four hours, based on the hypothesis that abundant fluid production reduces the efficacy of pleurodesis (Spiegler *et al.*, 2003).

The issue of rapid pleurodesis previously has been investigated. Villanueva *et al* (1994) were able to shorten the duration of chest tube drainage to an average of two days with no effect on response to pleurodesis. Spiegler *et al* (2003) have shown that pleurodesis can be accomplished within twenty four hours, and in many cases on the same day. Furthermore, the success of pleurodesis was accomplished with a small bore catheter.

In this prospective study, small bore pigtail catheters (Mar Flow[®] CH12) were used as an alternative for conventional thoracostomy tube (chest tube). This catheter is stronger and comes in with a trocar which is useful during insertion into the pleural space. The use of this pigtail catheter for pleural drainage in malignant pleural effusion has never been studied previously.

2. OBJECTIVE

The objective of this study was to determine the outcome of rapid pleurodesis using small bore pigtail catheter and bleomycin at four weeks follow up appointment. The outcome was determined by comparing chest radiography performed before rapid pleurodesis with chest radiography performed at four weeks post rapid pleurodesis. Outcome will be divided into three categories:

1. Success procedure when chest radiography at four weeks follow-up shows no accumulation of pleural fluid.
2. Partial success procedure when chest radiography at four weeks follow-up shows small amount of pleural fluid accumulation but patient is asymptomatic and did not require repeat pleural drainage.
3. Failed procedure when chest radiography at four weeks follow-up shows re-accumulation of fluid causing symptoms and the need for repeat pleural drainage.

3. PREVIOUS STUDIES

There were few studies that have been done to look for the successful of rapid pleurodesis in malignant pleural effusion and also the used of smaller thoracostomy tubes and the findings were as below:

- a) A rapid pleurodesis provide shorter hospital stay resulting in superior cost effectiveness and palliation without sacrificing the effectiveness of pleurodesis. In this prospective randomized study by Yildirim *et al* (2005), a comparison was made between rapid pleurodesis using small bore catheter (size 12 Fr) with standard protocol. In this study, rapid pleurodesis is performed by aspirating the pleural fluid at six hour intervals with instillation of oxytetracycline after each aspiration. They concluded that this new pleurodesis method provided shorter hospital stay resulting in superior cost-effectiveness and palliation without sacrificing the efficacy of pleurodesis. However, the range of drainage time was between 1.5 to 4.5 days.

- b) Chemical pleurodesis can be accomplished with good results in less than twenty four hours in majority of patients with malignant pleural effusions. In this study by Spiegler *et al* (2003), a small size thoracostomy tube (size 14 Fr) has been used to drain pleural effusion and chemical pleurodesis was performed using either bleomycin or talc two hours post pleural drainage. Of the twenty nine patients included in this study, twenty three patients (79%) did not require further intervention in subsequent follow-up.
- c) In another prospective randomized study, a comparison was made between Cystofix[®] catheter size CH10 and conventional large bore chest tube size CH24. It was concluded that pleurodesis in patients with recurrent malignant pleural effusion can be performed with a small percutaneous catheter with an effect to that obtained with a large bore chest tube and with less discomfort for the patient (Clements *et al.*, 1998).
- d) Parker, *et al* (1989) compared the drainage of pleural effusion using nephrostomy tube size 8.3 Fr or 10 Fr with conventional chest tube size 32 to 38 Fr. The aim of this study is to determine the effectiveness of the pleural drainage using small bore catheter. They concluded that percutaneous placement of small bore catheter appear to be adequate for the drainage of many malignant pleural effusion with less pain and better tolerated once the catheter is in place.

Based on the previous study results, it can be hypothesized that effective pleurodesis can be accomplished rapidly (within twenty four hours) using small bore catheter and bleomycin as sclerosing agent in patients with malignant pleural effusion.

4. MATERIAL AND METHODS

4.1 Study Design

This was a preliminary prospective study done at Hospital Universiti Sains Malaysia, Kubang Kerian and Hospital Raja Perempuan Zainab II, Kota Bharu with the involvement of Cardiothoracic, General Surgery, Orthopaedic (OORU), Oncology, Obstetric and Gynaecology and Radiology Units. The principle protocol of this study has been approved by Research Ethics Committee (Human), Universiti Sains Malaysia. This was a twelve month period study involving patients with malignant pleural effusion. Based on the single proportion formula, 138 subjects were needed for this preliminary prospective study. However, due to the small number of patients involved in this study, the initial prospective study has to be converted into case series study.

4.2 Subjects

There were five patients with malignant pleural effusions involved in this study. All patients have primary malignancy that have been diagnosed either by clinical presentation which was supported by radiological investigations or by tissue diagnoses before participating in this study. All patients were diagnosed with malignant pleural effusion based on clinical presentation of dyspnoea and supported by chest radiography. To prevent bias, the decision to include the subjects for this study and the insertion of pigtail catheter were made by medical officers who were not involved in this study.

4.3 Methods

Informed consent was taken before proceeding to insertion of the small bore pigtail catheter. A small bore pigtail catheter size 12 Fr (Figure 19) was inserted under aseptic technique and open method. All patients were given intravenous sedation with 5 milligrams of Midazolam prior to procedure. A local anaesthetic agent with 10 milliliters of 2% Lignocaine without adrenaline was given at the incision site. A two centimeters incision was made on the skin in the safety triangle (border of pectoralis major, latissimus dorsi and fifth intercostal space or at nipple line) and the wound deepened until intercostals space. An 18-gauge needle connected to a syringe was introduced (Figure 20). While aspirating, the needle was pushed until the effusion is freely aspirated. Using the 18-gauge needle as a landmark, a floppy tipped guide wire with a tapered mandril was inserted into the pleural space (Figure 20). The 18-gauge needle was then removed and using a vascular dilator (Figure 20), the tract was dilated and a 12 Fr pigtail catheter was introduced. Once the pigtail catheter was in place, the

floppy guide wire was removed. The pigtail catheter was anchored to the skin using Silk 0 suture. The drainage of pleural fluid began with pigtail catheter connected to low pressure suction at negative 20 cm H₂O (Figure 21).

All patients had a plain chest radiograph taken post procedure to assess the site of the pigtail catheter and also to assess any immediate complication that needs intervention. Sample of pleural fluid was taken and sent for biochemistry and cytology analysis. Drainage of the pleural fluid was continued for two hours. Drainage was withheld if the amount reached 1.5 liters before the 2-hour period.

Prior to instillation of Bleomycin, all patients received 10 milliliters of 2% Lignocaine injected into pleural space. Sixty units of Bleomycin diluted in 50 milliliters of Normal Saline were then instilled into the pleural space. The pigtail catheter was clamped for ninety minutes after instillation of Bleomycin. No change in position technique to equally distributed Bleomycin was adopted post instillation of the drug. The pigtail catheter was unclamped and the drainage was continued for another two hours before the catheter was removed. The pleurodesis process was carried out in spite of the amount of pleural fluid drained. The removal of pigtail catheter was also independent of the pleural fluid amount drained after instillation of bleomycin.

Post removal of pigtail catheter, chest radiography was performed for assessment. Patients were followed-up at four weeks period with repeat chest radiography. All chest radiographs were reviewed by radiologist. The success of the study was based on chest radiography findings and also patients' symptoms. The procedure was considered as success if the chest radiography at four weeks follow-up showed no accumulation of pleural fluid. Partial success was considered if the chest radiography at follow up showed small amount of pleural fluid accumulation but patient was asymptomatic. The procedure was considered fail if chest radiography showed re-accumulation of fluid causing symptoms and the need for repeated pleural drainage.

4.4 Inclusion and Exclusion Criteria

Patients with primary malignancy that presented with symptoms of dyspnoea and chest radiograph showed accumulation of pleural fluid malignant were included in this study. These patients were considered to have malignant pleural effusion. All patients who participated in this study were consented. Subjects were excluded from this study if blood was drained from pleural space after pigtail catheter was inserted, patient who died before the follow-up period, patients who developed complications post procedure that requires bigger drainage apparatus (tube thoracostomy), patients who had multiple pleurodesis performed prior to participating in this study and patients who refused informed consent.

5. CASE SERIES

Case 1

This patient was a 63 year old Chinese lady who was a known case of right breast cancer with advanced disease. Right mastectomy with axillary clearance was performed in 2007 and patient completed chemotherapy and radiotherapy. A CT scan abdomen and thorax performed six months after completed treatment showed distant metastases to liver and also lung. Patient was admitted to surgical ward under neurosurgical team with history of reduced in GCS associated with altered sensorium and right hemiparesis. Computer tomographic scan (Figure 4) and MRI of the brain (Figure 5) showed multiple lesions suggestive of brain metastases. Patient also had symptom of dyspnoea and CXR revealed right pleural effusion (Figure 6). Rapid pleurodesis was performed according to the protocol proposed. The procedure completed after 6 hours. Immediate post pleurodesis CXR showed improvement with aeration over the affected area. Patient was seen again in the clinic 4 weeks after pleurodesis with CXR showed no accumulation of pleural effusion and patient was asymptomatic (Figure 7). The pleural fluid biochemistry analysis and cytology came back as pH of 7.5 and no malignant cells seen.



Figure 1 – CT scan brain showed heterogeneously enhanced lesions with perilesional edema seen in the left centrum semiovale.

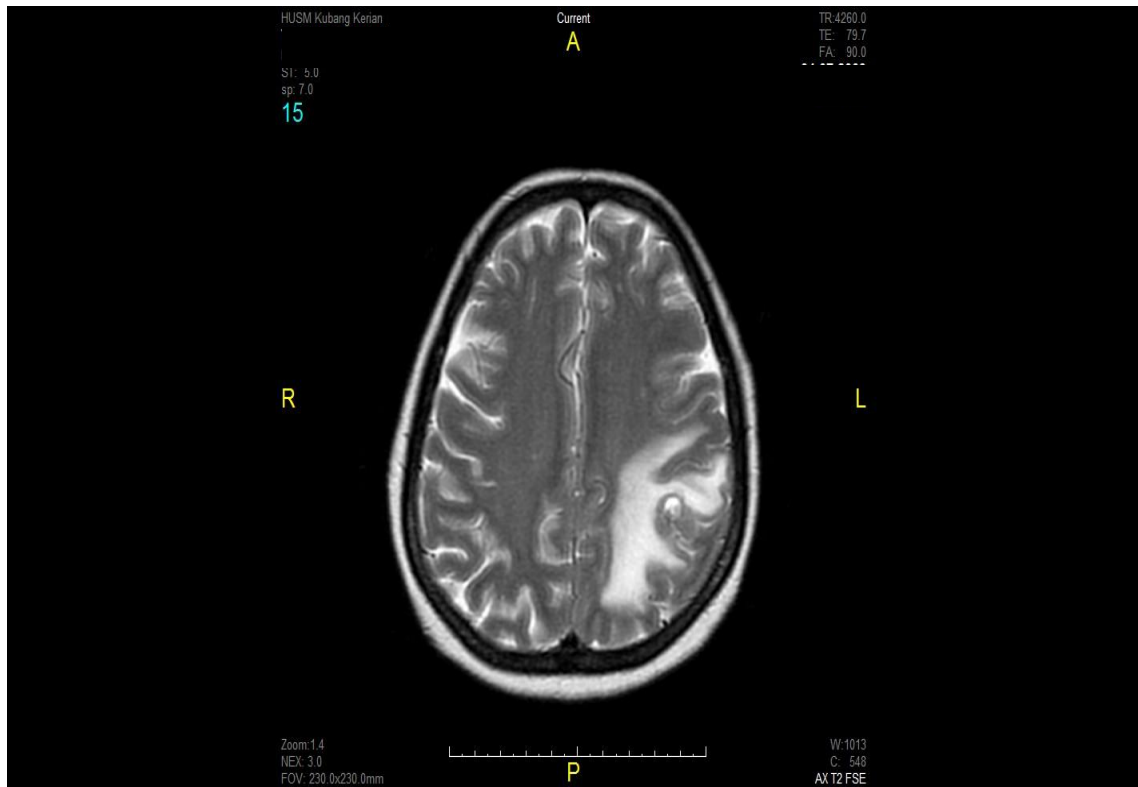


Figure 2 – MRI brain showed heterogeneously enhanced lesion with perilesional edema seen, hyperintense on T2 image.

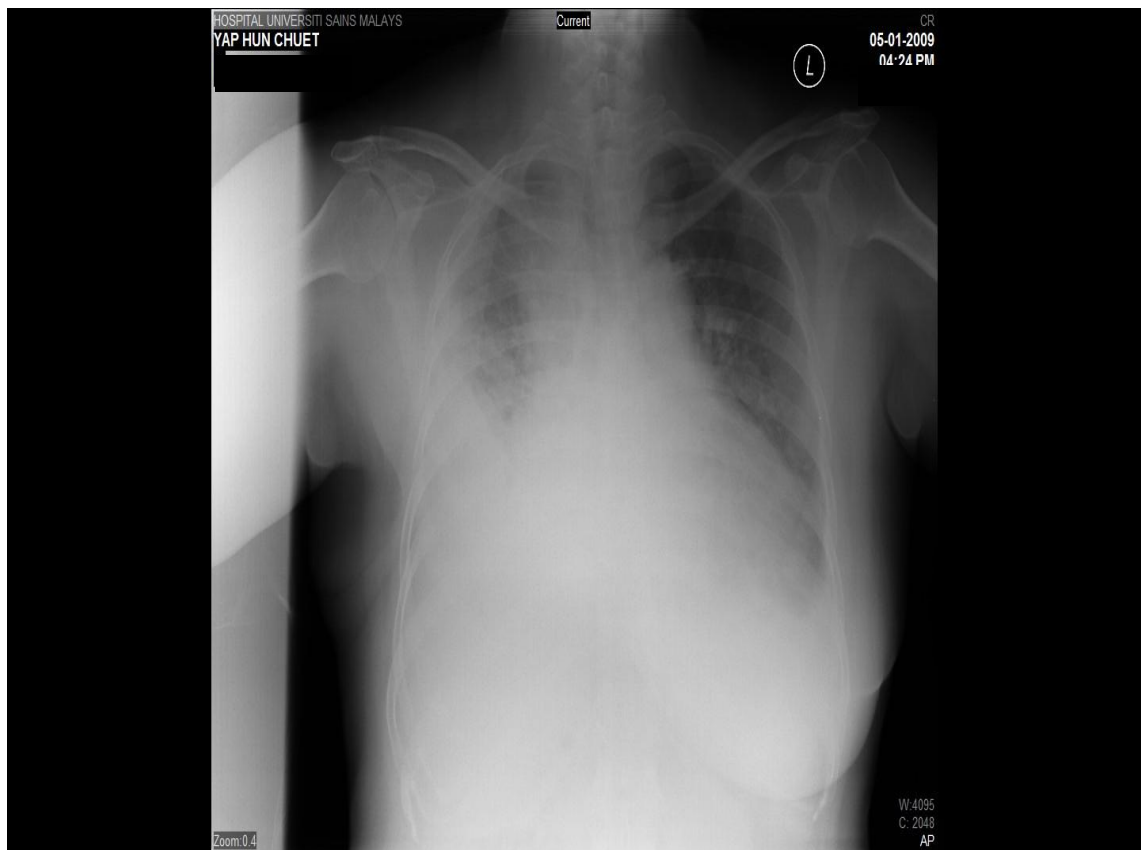


Figure 3 – Pre-insertion of pigtail catheter and pleurodesis CXR showed right opacity right lung suggestive of pleural effusion.

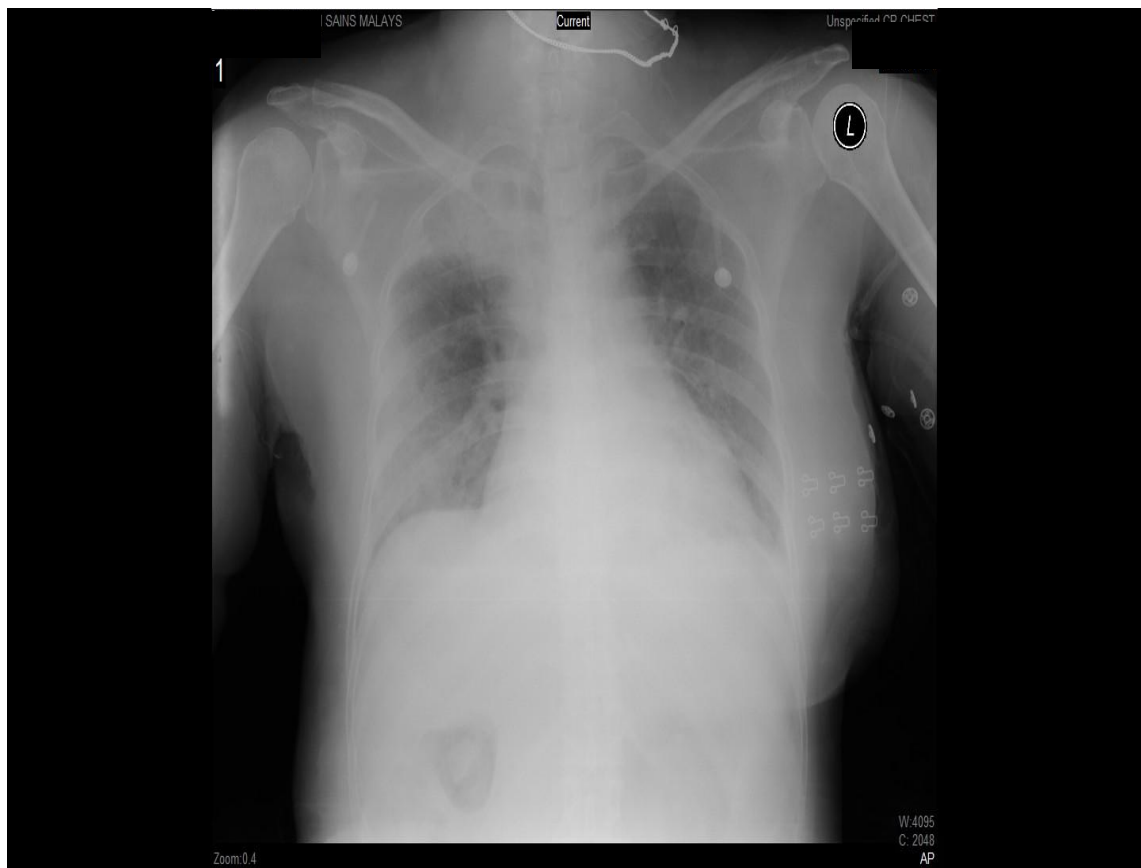


Figure 4 – Four weeks post pleurodesis CXR showed aeration of the right lung.

Case 2

This patient was a 38 year old Malay gentleman who presented to HUSM with symptoms of headache associated with left hemiparesis of 1 month duration. The symptoms were progressive and patient was unable to mobilize without any assistant. Patient was admitted under Neurosurgical team for further investigation. A CT scan of brain and thorax (Figure 8) performed showed perihilar mass over the right lung with massive pleural effusion and multiple brain lesions which suggestive of lung cancer as a primary pathology with brain metastasis. Patient also had dyspnoea at rest. Patient was consulted and agreed for pleurodesis. Rapid pleurodesis was performed according to protocol suggested. The procedure was performed in late afternoon and CXR post insertion of pigtail catheter was only done at midnight. The decision not to proceed with pleurodesis after midnight was made and thus, the drainage of pleural fluid was continued until morning. Pleurodesis was only performed at 10 o'clock the next morning. The whole procedure was completed after 18 hours. Immediate post pleurodesis CXR showed improvement with aeration over the upper and middle zones of the right lung (Figure 9). The symptom of dyspnoea was slightly improved and patient was discharged home 2 weeks after admission. Patient was again admitted to HUSM with symptom of seizure at home and dyspnoea was getting worse. A CXR on second admission (3 ½ weeks post pleurodesis) showed reaccumulation of pleural effusion (Figure 10) and large bore chest thoracostomy had to be inserted in view of the CXR finding and also symptom of dyspnoea. Pleural fluid analysis for biochemistry and cytology came back as pH of 6.9 and malignant cells seen.



Figure 5 – CT thorax showed right pleural effusion with thickening of pleura and atelectasis of right middle lobe.

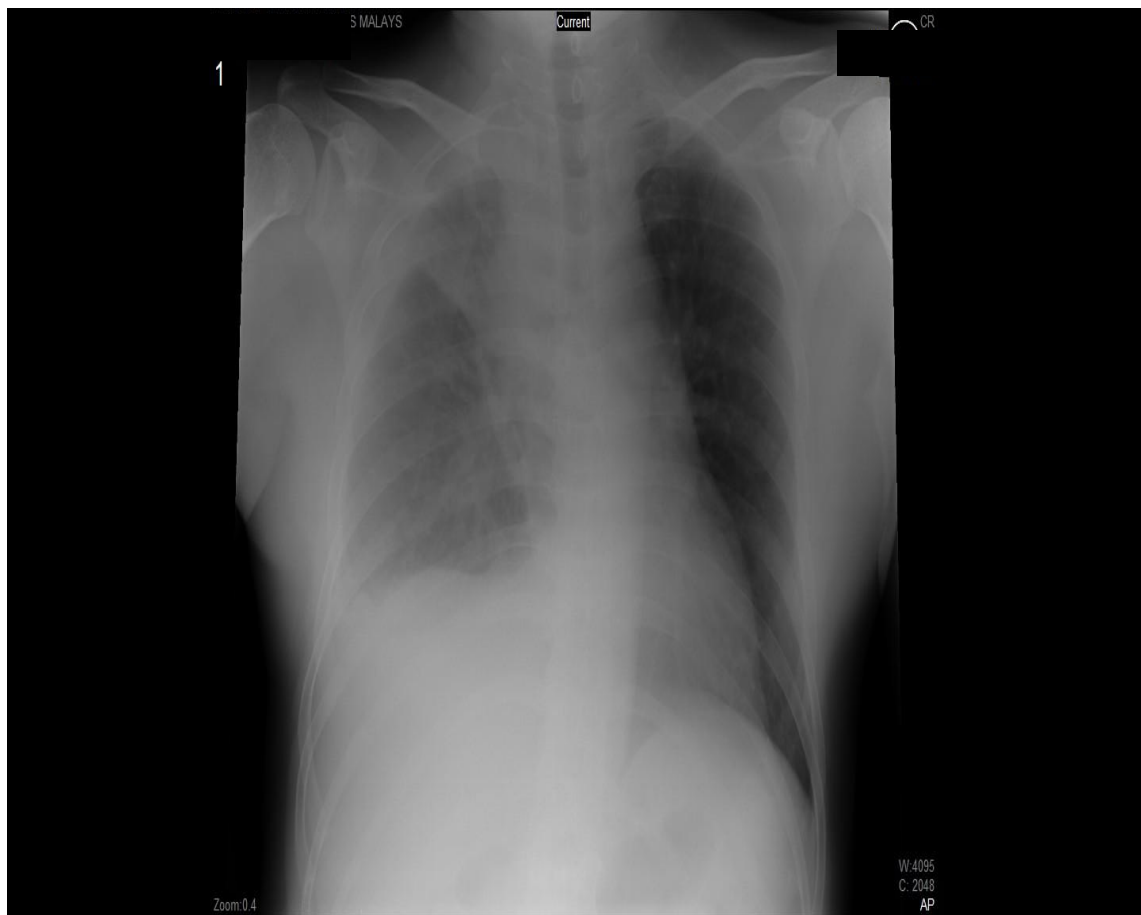


Figure 6 – Immediate CXR post pleurodesis showed aeration of the right upper and middle zones.

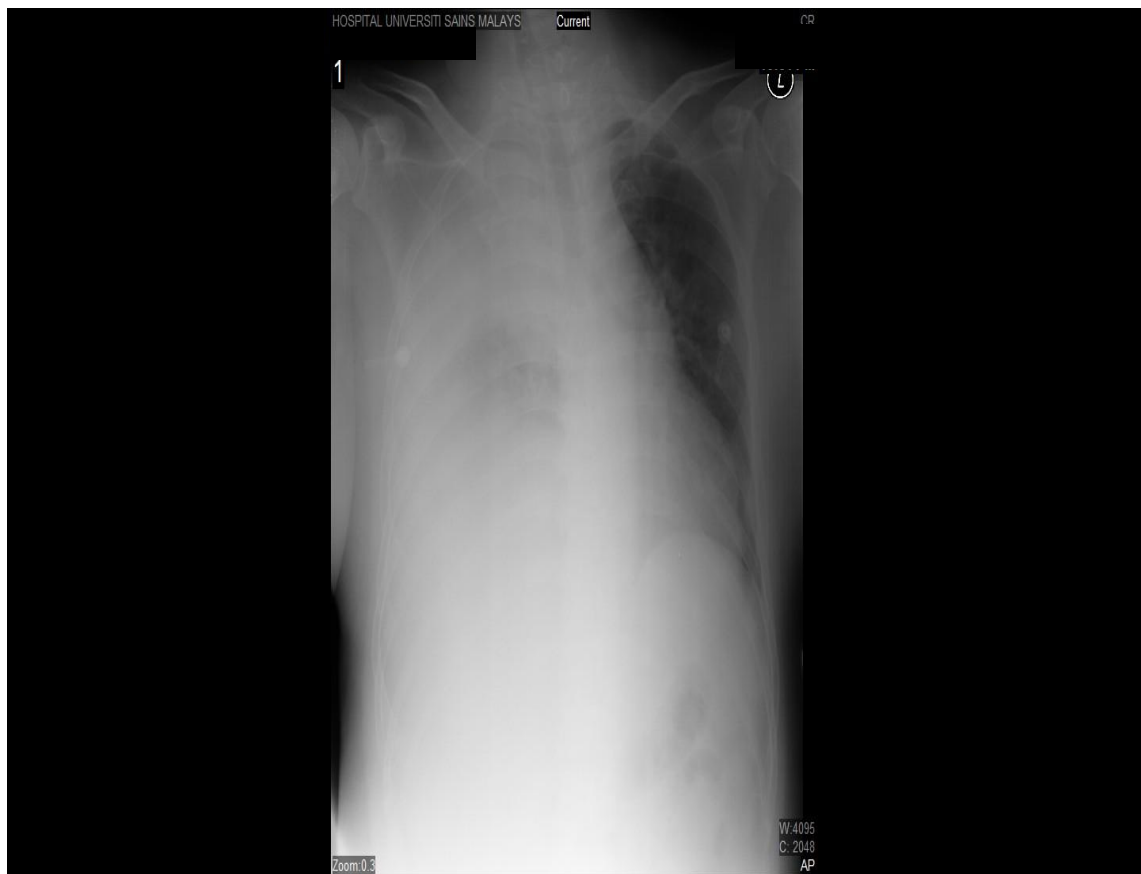


Figure 7 – CXR at 3 ½ weeks after pleurodesis showed reaccumulation of pleural effusion of right lung.